Remarks

The foregoing amendments to the pending claims add no new matter to the present application. The amendments to claims 34, 36, 48 and 70 are sought to correct the dependency of these claims upon cancellation of claim 28, and the amendments to claim 27 are supported throughout the specification, for example at page 7, lines 1-2, at pages 16-17, at pages 34-35, and throughout the Examples.

New claims 92-98 which are sought to be added are also fully supported in the application as filed, and therefore add no new matter. Specifically, new claim 92 is supported in the specification, *inter alia*, at page 26, lines 15-17, and at page 29, lines 1-5; new claims 93 and 94 are supported, *inter alia*, at page 29, lines 1-5; new claim 95 is supported, *inter alia*, at page 33, lines 15-19; new claim 96 is supported, *inter alia*, at page 34, lines 5-13; new claim 97 is supported, *inter alia*, at page 34, lines 14-29; new claim 98 is supported, *inter alia*, at page 35, lines 1-2; and new claim 99 is supported, *inter alia*, at page 35, lines 3-4.

Accordingly, the foregoing amendments do not add new matter, and their entry into the present application is respectfully requested. Upon entry of these amendments, claims 27, 29-37, 39-55, 60-72 and 92-99 are pending in the application, with claims 27, 29-31, 37, 39-43 and 60 being the independent claims.

II. Summary of the Interview

Applicants gratefully acknowledge the courtesies extended by Examiner Flood during a telephonic interview held on December 10, 2001, with George Jones, an attorney employee of the assignee of the present application, Invitrogen Corporation. A summary of the results of the interview is incorporated in the following remarks. During this interview, the Examiner and

Mr. Jones agreed that Group I as listed in Paper No. 7 contained a typographical error; *viz.*, claim 70, rather than claim 71, should have been indicated as a member of Group I. Accordingly, the remarks presented herein are directed to the inclusion of claim 70 in Group I.

III. Election of Group and Species

In reply to the requirement for restriction to one group for prosecution in the present application (Paper No. 7), Applicants provisionally elect group I (represented by claims 27-36, 70 and 72. In reply to the requirements for election of a single species upon election of group I (*see* Paper No. 7, page 3, section 5, second paragraph), Applicants provisionally elect agglomeration as the method of making a nutritive medium powder, water as the solvent, and dry powder medium as the starting material for making of the nutritive medium powder. These elections of group and species are made **with traverse**, for reasons presented below. Reconsideration and withdrawal of the restriction requirement and the requirement for election of species are respectfully requested.

A. Reasons for Traversal of Election of Species Requirement

With regard to the election of species requirement, it is respectfully believed that all of the claims restricted by the Examiner into group I are generic. Therefore, Applicants respectfully assert that the requirement for election of a single species is improper and should be withdrawn.

B. Reasons for Traversal of Restriction Requirement

With regard to the restriction requirement, Applicants note that the claims listed in Group IV and Group V include all of the limitations of claims listed in Groups I and II. Hence,

it is respectfully requested that the restriction of these claims into separate groups should be reconsidered and withdrawn. Should the Examiner not withdraw this restriction requirement, however, then Applicants respectfully contend that upon allowance of claims in either Group I or Group II, rejoinder of all of these groups would be proper. Applicants also note that if the non-elected restriction groups are withdrawn from consideration, then Applicants will consider amending the claims of Groups IV and V as prosecution progresses.

Applicants also remind the Examiner that the criteria for a proper requirement for restriction are that (1) the inventions must be independent or distinct as claimed; **and** (2) there must be a **serious burden** on the Examiner if restriction is not required. *See* MPEP § 803. For purposes of the initial requirement, a serious burden on the examiner may be *prima facie* shown if the examiner shows by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02. *See* MPEP § 803. In making the present restriction requirement, the Examiner states that the allegedly distinct inventions "have acquired a separate status in the art as shown by their different classification" and that therefore "restriction for examination purposes as indicated is proper." *See* Paper No. 7 at page 3, lines 16-18. Applicants respectfully disagree, and assert that the Examiner has failed to establish a *prima facie* case for serious burden for the reasons presented below.

1. Simultaneous Search of Groups I and II Is Proper

Applicants respectfully assert that the claims of at least Groups I and II should be grouped together for examination purposes, for several reasons. First, it is clear that certain limitations of the ingredients of the medium powders of Group I and of the supplements of Group II overlap. Generally, any ingredient that is suitable for a supplement must also be suitable for a medium

powder. As one of ordinary skill would appreciate, medium supplements are simply supplements -- they must be tolerated by the cells in the same way that the bathing medium is tolerated. Supplements may be added, *inter alia*, to culture specific cell strains or types (*e.g.*, a cell lacking an ability to synthesize an essential cell component), or may be added during culture as an ingredient is consumed by the cultured cells. Supplements thus may include a subset of the ingredients of a specific medium or may be used to "supplement," *i.e.*, to complete, a specific medium. For example, a medium or medium powder may be supplemented by a supplement such as a powdered serum to form a new medium or medium powder. Alternatively, the supplement may be added to a reconstituted medium or may be combined to form a dry powder for later reconstitution. In such a situation, as discussed in the present specification, the supplemented dry powder would thus contain the ingredients of the supplement:

> For example, a powdered nutritive medium may be mixed with a powdered serum (produced, for example, by spray-drying as described below) such as FBS at a serum concentration of about 0.1%, 0.2%, 0.5%, 1%, 2%, 2.5%, 5%, 7.5%, 10%, 15%, 20%, 25%, 50% or higher (w/w as a percentage of the powdered medium); the resulting powdered medium-serum mixture may then be agglomerated to produce an agglomerated medium-serum complex that will readily dissolve in a reconstituting solvent and thus be ready for use without further supplementation.

Specification at page 24, lines 18-25. In addition, the specification at pages 21 and 24 specifically discusses the use of supplements, powdered nutritive media, medium supplements, media subgroups and buffers. Each discussion specifically refers to sera, L-glutamine, cystine, hormones such as insulin, lipids (particularly phospholipids, sphingolipids, fatty acids and cholesterol), cytokines (particularly growth factors, interleukins, colony-stimulating factors and interferons) and neurotransmitters. Nowhere is there a statement in the specification that an ingredient of a supplement is unacceptable for use in a medium. Hence, the components of

media and supplements overlap to such an extent that a complete search of the subject matter of Group I would embody a complete search of the subject matter of Group II. Since the searches of these groups, if separate, would be so intertwined, searching the subject matter of both Groups I and II cannot properly be said to present a serious burden to the Examiner compared to searching the subject matter of only one of these groups. Similarly, a search of Group IV would encompass the subject matter of Group I, since the former is a method of using the latter. In addition, claims listed in Group V are dependent from claims listed in Groups I-III, such that a search of Group V would require a coextensive search of the subject matter in Groups I-III.

Accordingly, Applicants respectfully assert that the claims in Groups I-V are closely related in subject matter. As such, a search of one group of claims is likely to encompass subject matter pertinent to the patentability of all groups. Therefore, Applicants respectfully request that the restriction requirement be reconsidered and withdrawn. However, if the restriction requirement is not withdrawn *in toto*, it should at least be modified to combine groups I and II into a single restriction group, for the foregoing reasons and for the reasons presented in more detail below.

2. There Is No Basis for Classification Scheme of Groups I and II

In making the restriction requirement, the Examiner states that Group I, drawn to a nutritive medium powder, is classified in **class 435, First Line subclass 243**. *See* Paper No. 7 at page 2, section 1, lines 2-3. This class and subclass relate to microorganisms and culture media therefor. *See Manual of Classification*, http://www.uspto.gov/web/patents/classification/; *see also Examiner Handbook to the U.S. Patent Classification System*, "V. Selection of Locus for Searching or Placement, B. Selecting a Subclass Within a Class, paragraph 6," available at

http://www.uspto.gov/web/offices/pac/dapp/sir/co/examhbk/five.htm. The Examiner states that Group II, drawn to a nutritive medium supplement powder, is classified in **class 435, subclass 235**, which is a class/subclass that does not exist, **class 435, First Line subclass 325**, which relates to animal cells and culture media therefore, **class 435, First Line subclass 410**, which relates to plant cell, medium therefor, **class 435, Fifth Line subclass 255.21**, which relates to culture media, *per se* (and falls under First Line subclass 243 of Group I), and **class 435, Fourth Line subclass 254.2**, which relates to yeast and media therefor (and falls under First Line subclass 243 of Group I). *See id.*

Applicants respectfully assert that the Examiner has arbitrarily classified the subject matter of Groups I and II based on cell type when there is no basis in the claims for such delineation. The claims of Groups I and II do not limit the powder by cell type, as the Examiner has done in making the present restriction requirement. Hence, the Examiner has introduced limitations into the claims from the classification scheme, apparently in order to justify the restriction, when in fact there is no basis in the claims for the groupings. For example, the Examiner has placed the alleged invention of Group I into a class and subclass drawn to micro-organism culture media, while the alleged invention of Group II has been placed into classes and subclasses drawn to animal, plant and yeast cell culture media and culture media in general. Simply put, there are no such limitations in the claims upon which to base this classification scheme. Accordingly, Applicants respectfully assert that a proper search of the subject matter claimed in Group I would necessitate a search that would encompass at least Group II (and likely at least Groups III-V as well, as explained above). Hence, the first criterion for a proper restriction under MPEP § 803, that the claims be independent or distinct as claimed (as indicated by separate classification), has not been met.

3. Simultaneous Search of All Groups Would Not Impose a Serious Burden on the Examiner

Even assuming, *arguendo*, that there was a factual basis to the classification scheme of Groups I and II, the Examiner has failed to establish a serious burden of search. The classification of subject matter is based on class and subclass. Each indented heading (subclass) further qualifies the heading (subclass) under which it is indented and, consequently, must be read as including all of the limitations of the superior heading (subclass). *See Examiner Handbook to the U.S. Patent Classification System*, "V. Selection of Locus for Searching or Placement, B. Selecting a Subclass Within a Class, paragraph 5," available at http://www.uspto.gov/web/offices/pac/dapp/sir/co/examhbk/five.htm. Therefore, search of an indent subclass (Second Line subclass, Third Line subclass, etc.), would also require a search of the heading (subclass) under which it is indented. Alternatively, search of an indented subclass would also encompass search of the heading under which it is indented because the former contains all the limitations of the latter.

The purported search of Group II requires the search of a class and subclass that does not exist (435/235) and the search of two classes and subclasses (435/255.21 and 435/254.2) that fall within the class and subclass of Group I (and which therefore contain all the limitations of class 435, subclass 243). Therefore, the search of Groups I and II would be co-extensive, even based on the classification scheme put forth by the Examiner. The search of Group IV would also be co-extensive with the search of Group I, since the former is a method of using the latter. Further, the kit of Group V is classified in class 435, subclass 810, which is drawn to a packaged device or kit. The novelty of the alleged invention, however, is in the components of the kit, which has

been classified into Groups I-III. Therefore, as noted above, a proper search of Group V would also require a search of Groups I-III.

Clearly, then, for the reasons outlined above, searches of Groups I, II, IV and V even under the Examiner's purported classification scheme would be co-extensive. Hence, no serious burden would be imposed on the Examiner if restriction was not required and a search of all groups was performed. Thus, the second requirement set forth in MPEP § 803 has not been met.

It should be noted that the two requirements set forth in MPEP § 803 are connected with "and;" hence, satisfaction of both is required. As discussed above, however, neither of these requirements has been met: it has not been shown that the allegedly distinct inventions are, indeed, distinct; and it has not been shown by appropriate explanation that a serious burden would be imposed on the Examiner if restriction were not required. Accordingly, "[i]f the search and examination of an entire application can be made without serious burden, the examiner must examine it on the merits, even though it includes claims to distinct or independent inventions." MPEP § 803. Hence, reconsideration and withdrawal of the restriction requirement and the requirement for election of species, and consideration and allowance of all pending claims, are respectfully requested.

IV. Conclusion

Applicants believe that the present application is in condition for immediate examination on the merits. If the Examiner believes, for any reason, that personal communication will expedite prosecution of this application, the Examiner is invited to telephone the undersigned at the number provided.

Prompt and favorable consideration of the foregoing amendments and entry of the same into the present application, and reconsideration and withdrawal of the requirements for restriction and election of species, are respectfully requested.

Respectfully submitted,

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Version with markings to show changes made

In the Claims:

(a) Claim 28 has been cancelled without prejudice or disclaimer.

(b) Claims 27, 34, 36, 48 and 70 are sought to be amended as follows:

27. (Twice amended) A eukaryotic nutritive medium powder prepared by agglomerating a dry powder eukaryotic nutritive medium with a solvent.

34. (Once amended) The nutritive medium powder of any one of claims [27-31] claims 27 and 29-31, wherein said nutritive medium powder comprises at least one buffer salt.

36. (Once amended) The nutritive medium powder of any one of claims [27-31] 27 and 29-31, wherein said nutritive medium has a pH of between 7.1-7.5 when said medium is reconstituted with a solvent.

48. (Once amended) A method of culturing a cell comprising reconstituting the nutritive medium powder of any one of claims [27-31] 27 and 29-31 with a solvent to form a liquid solution and contacting the cell with said liquid solution under conditions favoring the cultivation of the cell.

70. (Twice amended) A kit for use in the cultivation of a cell, said kit comprising one or more containers wherein a first container contains the powder of any one of claims [27-31] 27, 29-31, 37, 39-43 and 60.

(c) New claims 92-99 are sought to be entered.